

REMARKS

Applicant appreciates the Examiner's thorough examination of the subject application and requests reconsideration of the subject application based on the following remarks.

Claims 1-30 are pending in the subject application. Claims 27 and 30 have been amended for clarification purposes. Claims 31-34 have been added. Support for the amendments to claims 27 and 30 and for added claims 31-34 is found throughout the Specification, as filed, and no new matter is presented by the amendment.

Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

35 U.S.C. §102 Rejections

Claims 1-30 have been rejected under 35 U.S.C. §102(e) as being anticipated by Cesarczyk et al (USP 6,150,178). The Office asserts that:

Cesarczyk et al. teach a method and device for sample collection comprising an elongated handle having an absorbent foam member that is slidably receivable in a housing. The housing contains a test membrane capable of detecting analytes of interest in the sample. The housing is of a diameter smaller than the housing such that when the handle is pulled through the sample is expressed from the foam member and contacts the membrane.

Applicants respectfully traverse.

Applicants claim, in claim 1, a specimen collecting and testing device comprising (1) an elongate, hollow housing, (2) at least one elongate handle member, having a proximal end and a distal end, slidably received in the hollow portion of the housing, and (3) a foam member, for collecting specimen, extending from the proximal end of the handle whereby, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber and onto the test membrane or sample collecting strip. As further set out, the elongate, hollow housing includes (a) a proximal end, (b) a distal end, (c) a hollow portion, (d) at least one test membrane or sample collecting strip positioned within the hollow portion of the

housing, the test membrane carrying diagnostic test chemistry, and (e) a fluid chamber, for holding specimen, adjacent to the test membrane or sample collecting strip.

Applicants have, thus, provided an improved specimen collecting and testing device that includes, within a hollow housing holding the test membrane, a fluid chamber. The fluid chamber is positioned within the hollow housing adjacent to the test membrane such that when the handle is drawn into the housing, the foam member is compressed to expel collected sample. This expressed sample is deposited into the fluid chamber. Subsequently, the sample is deposited onto the test membrane. This provides additional advantages and increased accuracy in test results because with the prior devices, all of the expressed sample is directly deposited onto the test membrane. If a large amount of specimen is collected by the foam member, excess specimen may be deposited onto the test membrane, which can negatively impact test results. The present invention, on the other hand, provides a fluid chamber into which the specimen is deposited prior to subsequent delivery to the test membrane. The fluid chamber, thus, can prevent the deposit of excess specimen by only holding as much specimen as the fluid chamber can hold. Thus, the fluid chamber can be metered to hold only a certain amount of specimen which is the optimal amount for a particular test.

It is well established that to anticipate a claim, the reference must teach every element of the claim. As set out in MPEP §2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, all words in a claim must be considered in judging the patentability of that claim against the prior art.

Cesarczyk '178 describes a diagnostic testing device comprising a housing containing a test membrane, an elongated handle slidably received in the housing, and a foam member extending from the elongated handle. As the handle is drawn into the housing, specimen collected on the foam member is expressed directly onto the test

membrane. Cesarczyk '178 does not describe or otherwise suggest a fluid chamber for holding specimen deposited from the foam member.

It has been asserted by the Office that the hollow portion of the housing could be interpreted to be a fluid chamber. Applicants respectfully disagree. As set out above, Applicants' claim, among others, the following separate elements: (1) an elongate, hollow housing having (c) a hollow portion, (e) a fluid chamber, for holding specimen, positioned positioned within the hollow portion adjacent to the test membrane or sample collecting strip. Thus, Applicants' claim 1 requires that the housing have a hollow portion of the housing and a fluid chamber. Thus, by this assertion, the Office is essentially reading an element out of Applicants' claims rather than considering all elements of the claim as required.

Accordingly, Applicants respectfully submit that claim 1 is not anticipated by Cesarczyk '178. Namely, Cesarczyk '178 does not teach each and every element of Applicants' claim 1 as required to establish anticipation. Claims 2-21 and 26 depend from claim 1 and, likewise, are not anticipated by Cesarczyk '178.

Applicants claim, in claim 22, a method of collecting a sample of fluid specimen for diagnostic testing, the method comprising: (1) providing a specimen collecting and testing device that includes (a) an elongate, hollow housing having (i) a proximal end, (ii) a distal end, (iii) at least one test membrane or sample collecting strip positioned within the housing, (iv) a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip and having an aperture positioned adjacent to the test membrane or sample collecting strip, (b) at least one elongate handle member, having a proximal end and a distal end, slidably received in the housing, and (c) a foam member, for collecting specimen, extending from the proximal end of the handle; (2) wetting the foam member with specimen; (3) positioning the device vertically with the foam member extending upwards; (4) sliding the handle member through the housing, thereby drawing the wetted foam member across the fluid chamber and delivering the collected specimen to the fluid chamber; and (5) positioning the device horizontally so as to level off the specimen in the fluid chamber

and allow the specimen to flow through the aperture and onto the test membrane or sample collecting strip.

As set out above, Cesarczyk '178 does not teach or even suggest a fluid chamber. Further, Cesarczyk '178 does not describe a fluid chamber having an aperture positioned adjacent to the test membrane or sample collecting strip. Thus, Cesarczyk '178 does not teach providing a specimen collecting and testing device as specified in claim 22. Further, Cesarczyk does not teach a method wherein the foam member is wetted with specimen, the device is positioned vertically with the foam member extending upwards, sliding the handle member through the housing, thereby drawing the wetted foam member across the fluid chamber and delivering the collected specimen to the fluid chamber and positioning the device horizontally so as to level off the specimen in the fluid chamber and allow the specimen to flow through the aperture and onto the test membrane or sample collecting strip. As set forth, Cesarczyk '178 describes a diagnostic testing device comprising a housing containing a test membrane, an elongated handle slidably received in the housing, and a foam member extending from the elongated handle. As the handle is drawn into the housing, specimen collected on the foam member is expressed directly onto the test membrane. Cesarczyk '178 does not teach or even suggest a fluid chamber or an aperture in a fluid chamber nor does Cesarczyk '178 teach or even suggest a method wherein specimen from the foam member is delivered to a fluid chamber while the device is positioned vertically and, subsequently, positioning the device horizontally so as to level off the specimen in the fluid chamber and allow the specimen to flow through the aperture and onto the test membrane.

Again, as set out above, the hollow portion of the housing of Cesarczyk '178 could not be considered a fluid chamber because the fluid chamber is a separate element of the housing that is positioned within the hollow portion. Further there is no aperture as taught by Applicants', which conveys the specimen from the fluid chamber to the test membrane.

Accordingly, claim 22 is not anticipated by Cesarczyk '178. Cesarczyk '178 does not teach each and every element of the claim. Namely, Cesarczyk '178 does not

teach (1) providing a specimen collecting and testing device that includes a fluid chamber having an aperture, (2) drawing the wetted foam member across the fluid chamber and delivering the collected specimen to the fluid chamber or (3) and positioning the device horizontally so as to level off the specimen in the fluid chamber and allow the specimen to flow through the aperture and onto the test membrane or sample collecting strip. Claims 23-25 depend from claim 22 and, likewise, are not anticipated by Cesarczyk '178.

Applicants claim in claim 27 a specimen collecting and testing device comprising a sample collecting mechanism and a sample testing mechanism. The sample collecting mechanism comprises an elongate, hollow housing having a proximal end and a distal end and a hollow portion, an elongate handle member slidably mounted within the hollow portion of the housing, a foam member for collecting specimen extending from the proximal end of the handle. The sample testing mechanism comprises at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the hollow portion of the housing; and a fluid chamber, for holding specimen, within the hollow portion of the housing adjacent to the test membrane or sample collecting strip.

As set out above, Cesarczyk '178 does not teach or even suggest a specimen collecting and testing device having a fluid chamber, for holding specimen, within the hollow portion of the housing adjacent to the test membrane or sample collecting strip. Further, set out above regarding claim 1, Applicants' claim the following separate elements: (1) an elongate, hollow housing having (c) a hollow portion, (e) a fluid chamber, for holding specimen, positioned positioned within the hollow portion adjacent to the test membrane or sample collecting strip. Thus, Applicants' claim 27 requires that the housing have a hollow portion of the housing and a fluid chamber. Thus, the hollow of the housing in Cesarczyk '178 could not be interpreted to be a fluid chamber.

Accordingly, claim 27 is not anticipated by Cesarczyk '178. Claims 28-29 depend from claim 27 and, likewise, are not anticipated by Cesarczyk '178.

Applicants claim, in claim 30 a specimen collecting and testing device comprising an elongate, hollow housing having a proximal end and a distal end, an elongate handle member having a proximal end and a distal end, the handle member slidably mounted within the housing, the elongate handle member and housing being coaxial, a foam member for collecting specimen extending from the proximal end of the handle, at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the housing, and a fluid chamber for holding specimen positioned adjacent to the test membrane or sample collecting strip, the fluid chamber having an aperture, whereby specimen collected by the foam member is deposited into the fluid chamber, through the aperture and onto the test membrane.

As set out above, Cesarczyk '178 does not describe or suggest a fluid chamber for holding specimen positioned adjacent to the test membrane or sample collecting strip. Further, Cesarczyk '178 does not teach or suggest a the fluid chamber having an aperture, whereby specimen collected by the foam member is deposited into the fluid chamber, through the aperture and onto the test membrane. Rather, Cesarczyk '178 describes a diagnostic testing device comprising a housing containing a test membrane, an elongated handle slidably received in the housing, and a foam member extending from the elongated handle. As the handle is drawn into the housing, specimen collected on the foam member is expressed directly onto the test membrane.

As further set out above, the hollow of the housing of Cesarczyk '178 could not be a fluid chamber in accordance with Applicants' teaching. In particular, in claim 30, Applicants claim a fluid chamber for holding specimen positioned adjacent to the test membrane or sample collecting strip, the fluid chamber having an aperture, whereby specimen collected by the foam member is deposited into the fluid chamber, through the aperture and onto the test membrane. In Cesarczyk '178, if the hollow portion of the housing was interpreted to be a fluid chamber, there is no aperture in the hollow of the housing whereby specimen collected by the foam member is deposited into the hollow of the housing ("fluid chamber"), through the aperture and onto the test membrane. The only "apertures in the Cesarczyk '178 device are at either end of the housing. However, the apertures are not such that specimen collected by the foam

member is deposited into the hollow of the housing ("fluid chamber"), through an aperture (through either end of the housing out of the housing) and onto the test membrane (which is inside the housing).

Thus, claim 30 is not anticipated by Cesarczyk '178.

Further, claims 31-34 are not anticipated by Cesarczyk '178. These claims contain the claim elements set forth in claims 1, 22, 27 and 30. Further, claim 31 sets out that the fluid chamber is positioned within the hollow portion of the housing adjacent to the test membrane or sample collecting strip. Thus, claim 31 further points out that the fluid chamber and the hollow portion of the housing are two separate elements. The fluid chamber is an element positioned in the hollow portion element. Thus, the hollow portion of the Cesarczyk '178 device could not be the fluid chamber because the fluid chamber is a distinct element. Claim 32 further points out that the fluid chamber is sized for holding specific volumes of specimen and that the device is positioned horizontally so as to level off the specimen in the fluid chamber, and so as to allow specimen in excess of the volume of the fluid chamber to flow out of the fluid chamber. Cesarczyk '178 in no way teaches or suggests any of these elements. Claim 33 further points out that the fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip whereby, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber prior to being deposited onto the test membrane or sample collecting strip. Cesarczyk '178 does not describe or suggest this in any way. Rather, according to Cesarczyk '178, sample deposited from the foam member is deposited directly onto the test membrane and does not pass into any intermediate chamber as set forth in claim 33. Claim 34 further points out that the fluid chamber is sized so as to hold specific volumes of specimen, and whereby only the specific volume of specimen is deposited from the fluid chamber onto the test membrane. This is in no way taught or suggested by Cesarczyk '178. Cesarczyk '178 does not teach a fluid chamber or a fluid chamber sized to hold only a specific volume of specimen such that only the specific volume of specimen is deposited from the fluid chamber onto the test membrane.

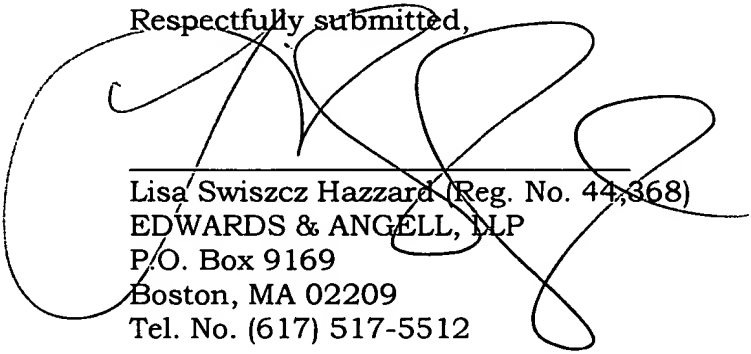
CONCLUSION

Reconsideration and allowance of claims 1-34 is respectfully requested in view of the foregoing discussion. Further, withdrawal of the restriction requirement is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

Applicants conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,



Lisa Swiszc Hazzard (Reg. No. 44,368)
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209
Tel. No. (617) 517-5512